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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,520	07/25/2005	Jean-Paul Remon	50304/083001	9447

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EXAMINER	
THEODORE, MACALI P	

ART UNIT	PAPER NUMBER
1791	

NOTIFICATION DATE	DELIVERY MODE
11/17/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No.	Applicant(s)	
	10/536,520	REMON ET AL.	
	Examiner	Art Unit	
	Magali P. Théodore	1791	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-58* is/are pending in the application.

4a) Of the above claim(s) *39-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 May 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/25/2005, 9/26/2005, 10/14/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

1. Applicant's election without traverse of claims 45-58 in the reply filed on October 14, 2008 is acknowledged.

2. Claims 39-44 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 14, 2008.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 51 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 51 recites "a poorly soluble drug belonging to Class II or Class IV of the Biopharmaceutical Classification System." That recitation is indefinite first because "poorly" is a relative term and second because the Biopharmaceutical Classification System is subject to change. For the sake of compact prosecution, the recitation has been interpreted to mean "a therapeutic agent selected from the following list: beta-blockers, calcium antagonists, ACE inhibitors, sympathomimetic agents, hypoglycemic agents, contraceptives, alpha-blockers, diuretics, anti-hypertensive agents, anti-psoriatics, bronchodilators, cortisones, anti-mycotics, salicylates, cytostatics, antibiotics, virustatics, antihistamines, UV-absorbers, chemotherapeutics, antiseptics, estrogens,

scar treatment agents, antifungals, antibacterials, antifolate agents, cardiovascular agents, nutritional agents, antispasmodics, analgesics, antipyretics, anti-inflammatory agents, coronary vasodilators, peripheral vasodilators, antitussive, muscle relaxants, tranquilizers, antiarrythmic agents, anticoagulants, antiemetics, expectorants and antidiabetic agents."

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 45, 47, 52-53 and 55-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Sugano et al. (US 4,416,606, "Sugano").

Regarding claim 45, Sugano teaches a continuous wet granulation method (col 1 ln 5-7) comprising the steps of by feeding a powder (sodium percarbonate, col 6 ln 8) to a first transport zone (fig 1 zone I), feeding a liquid (aqueous solution, col 6 ln 11) into the same transport zone, continuously advancing the resulting mixture from the transport zone to an agglomeration zone downstream (fig 1 zone II_1), transporting the mixture to a second transport zone further downstream (fig 1 zone II_2) and discharging the resulting granules without submitting them to any pressure gradient (fig 5 part 8).

Regarding claim 47, Sugano teaches a twin screw (fig 1 part 2).

Regarding claim 52, Sugano teaches that the powder is a chemical (sodium percarbonate, col 6 ln 8).

Regarding claim 53, Sugano teaches that the weight of the liquid is about 2 % of the weight of the powder (2 liters of aqueous solution per 20 kg of powder equals 1 %, col 6 ln 10-13).

Regarding claims 55-56, Sugano teaches drying and dry-milling the discharged granules (col 5 ln 11-16).

Claim Rejections - 35 USC § 102/103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claim 58 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over either Sugano or Gamlen.

Each of the disclosed products of Sugano and Gamlen (tablets and pellets, In 5-6) and the instantly claimed product appear to be essentially the same, made of the same components, and used in the same manner.

In the event any differences can be shown for the product of the product-by-process claim 58 as opposed to the product taught by the prior art, such differences would have been obvious to one of ordinary skill in the art as a routine modification of the product in the absence of a showing of unexpected results. See *In re Thorpe*, 227 USPQ 964 (Fed. Cir. 1985). Also, when the examiner has found a substantially similar product as in the applied prior art, the burden of proof is shifted to applicant to establish that their product is patentably distinct and not the examiner to show the same process of making. *In re Brown*, 173 USPQ 685 and *In re Fessmann*, 180 USPQ 324.

Claim Rejections - 35 USC § 103

11. Claims 46 and 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sugano as applied to claim 45 above.

Regarding claim 46, Sugano does not teach additional agglomeration or transport zones. However, it would have been obvious to one of ordinary skill in the art to duplicate those zones and the corresponding steps in order to effect more agglomeration. It has been held that mere duplication of parts has no patentable significance unless a new and unexpected result is produced. See MPEP 2144.04 VI B, in re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960).

Regarding claim 54, Sugano does not specify an operating temperature. However, Sugano suggests that temperature as a result effective parameter by teaching cooling of the apparatus (col 4 ln 61-64). Therefore it would have been obvious to one of ordinary skill in the art to optimize the operating temperature because Sugano teaches cooling. Optimizing a result-effective parameter known in the art does not impart patentable distinction to an invention. See MPEP 2144.05 [R-5] II, in re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

12. Claims 45-46, 48-54 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gamlen et al. (1986, "Gamlen") in view of Sugano.

Regarding claim 45, Gamlen et al. teach mixing powder and liquid (p 1705) and granulating the mixture to make pharmaceutical pills (p 1702 ln 3-7).

Gamlen's method involves the continuous (introduction, first line) extrusion of the mixture through a perforated plate (p 1705 ln 5-8). However, Sugano teaches that extruding the mixture through a perforated plate requires one to constantly replace the clogged plate (col 1 ln 33-39). Sugano's remedy is a method comprising the steps of by feeding a powder (sodium percarbonate, col 6 ln 8) to a first transport zone (fig 1 zone I), feeding a liquid (aqueous solution, col 6 ln 11) into the same transport zone, continuously advancing the resulting mixture from the transport zone to an agglomeration zone downstream (fig 1 zone II_1), transporting the mixture to a second transport zone further downstream (fig 1 zone II_2) and discharging the resulting granules without submitting them to any pressure gradient (fig 5 part 8). Therefore it would have been obvious to one of ordinary skill in the art to replace the extrusion steps taught by Gamlen with the steps taught by Sugano because Sugano's steps eliminate the problem of the stopped-up extrusion plate.

Regarding claim 48, Gamlen does not specify a residence time. However, in any agitation process involving powder and liquid, powder needs time to absorb the liquid. Gamlen suggests that residence time is a result effective variable by proposing it as the object of further study (p 1713, Conclusion, part b). Therefore it would have been obvious to one of ordinary skill in the art to optimize the residence time of the mixture in the machine. Optimizing a result-effective parameter known in the art does not impart patentable distinction to an invention. See MPEP 2144.05 [R-5] II, in re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Regarding claims 49-52, Gamlen teaches that the powder is about 80 % paracetamol, an analgesic.

Regarding claim 53, Gamlen teaches that the weight of the liquid is about 16 % of the weight of the powder (15.3 kg / 70 kg = 25 %, p 1705 last two lines -p 1706 ln 1-3).

Regarding claim 54, Gamlen does not specify an operating temperature. However, Gamlen suggests that temperature as a result effective parameter by teaching cooling of the mixture throughout the process (p 1705 ln 10). Therefore it would have been obvious to one of ordinary skill in the art to optimize the operating temperature because Gamlen teaches constant cooling. Optimizing a result-effective parameter known in the art does not impart patentable distinction to an invention. See MPEP 2144.05 [R-5] II, in re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Regarding claim 57, Gamlen teaches that the powder includes hydroxypropyl methyl cellulose (abstract ln 4, p 1705 formula 2).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Magali P. Théodore whose telephone number is (571) 270-3960. The examiner can normally be reached on Monday through Friday 9:30 a.m. to 6:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina A. Johnson can be reached on (571) 272-1176. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. P. T./
Examiner, Art Unit 1791
/Christina Johnson/
Supervisory Patent Examiner, Art Unit 1791